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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,819	05/26/2000	Vadim Vladimirovich Yuzhakov	7606R	9337

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EXAMINER

DESANTO, MATTHEW F

ART UNIT PAPER NUMBER

3763

DATE MAILED: 10/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/580,819

Applicant(s)

YUZHAKOV ET AL.

Examiner

Matthew F DeSanto

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 8-12 and 20-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 13-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-4, 6, 13-17, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Allen et al. (USPN 6,334,856).

Allen et al. discloses a microneedle array comprising a plurality of microneedles with a plurality of projections which extend from the second side of said base element and wherein said projections are spaced by a range of 50-1000 micron (Column 14, lines 18-20) and wherein said length of projections are 50-3000 micron (Column 5, lines 39-58). (Figures 1A, 1B, 3G, 4D, and Entire reference)

3. Claims 1 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Gerstel et al. (USPN 3,964,482).

Gerstel et al. discloses the microneedle array comprising a plurality of microneedles with a plurality of projections which extend from the second side of said base element and wherein said projections are spaced by a range of 50-1000 micron

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(Column 7, lines 42-45) and wherein said length of projections are 50-3000 micron (Column 7, lines 64-65).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-7 and 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al. as applied above, and further in view of Reed et al. (USPN 5676850).

Allen et al. disclosed the claimed invention except for the hollow element having at least two sharp projections proximal to an end of the hollow element.

Reed et al. disclosed an hollow elements each exhibit an edged outer contour, in a transverse plane, that is perpendicular to a longitudinal axis of said hollow element, said outer contour having at least 2 shape projections (Figure 7, 13 and entire reference)

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the device of Allen et al. with the teachings of Reed et al. because Reed et al. discloses a more efficient way to anchor the infusion structure to the organ body.

Therefore, it would have been obvious to one of ordinary skill in the art to combine Allen et al. with Reed et al. to obtain the invention as specified in claims 1-7 and 13-19.

Response to Arguments

6. Applicant's arguments filed 8/12/03 have been fully considered but they are not persuasive.

The Applicant first argues that Allen et al. and Gerstel et al. does not teach the separation distance and the length of the microneedles. Allen teaches this is in Column 14, lines 18-20 and Column 5, lines 39-58; and Gerstel et al. teaches it in (Column 7, lines 42-45) and (Column 7, lines 64-65).

7. The applicant next argues that the amendment made over comes the prior art. The examiner disagrees with this statement, because this statement is disclosed in Allen et al. and Gerstel et al. as well as being inherently taught because since the apparatus of Allen et al. or Gerstel et al. is used to penetrate the skin, it would have to be sharp at an edge to pierce the skin layer.

8. Finally, the applicant argues that if Reed et al. was combined with Allen et al., the claimed invention would not be formed. This is not true, the claimed invention would be formed, but the reason for combining would be different then the reason the Applicant's invention is intended for. The reason to combine would be to allow the "barbs" to maintain the infusion device in the organ, and thus making the apparatus comprise the structural limitations of the claimed invention. The applicant is arguing the intended use, and therefore, since this applicant is an apparatus claim, if the apparatus is capable of performing that function then the prior art rejection would read on the claimed invention. Since Fig. 13 of Reed et al. show the "barbs" to pierce and maintain the microneedles in the organ, the examiner maintains the rejection because the

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combined rejection of Allen et al. with Reed et al. would be an apparatus with microneedles that would be spaced according, have the proper length and have the sharp end projections as the end of the hollow needle.


Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 9:30-6:00.


Matthew DeSanto
Art Unit 3763
October 8, 2003


BRIAN L. CASLER
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